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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,629	10/18/2004	Akihiro Umezawa	Q84193	7035

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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,629	UMEZAWA ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment received 10/18/04 is acknowledged. Claims 1-29 are currently pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, drawn to a method of forming pancreatic β cells from mesenchymal cells comprising contacting said mesenchymal cells with a pancreatic β cell-forming agent.

Group II, claim(s) 10-14 and 25, drawn to a pancreatic β cell-forming agent.

Group III, claim(s) 15-24, drawn to a method of identifying pancreatic β cell-forming agents comprising contacting mesenchymal cells with candidate substances.

Group IV, claim(s) 26, drawn to a method of treating a patient with impaired glucose tolerance comprising administering pancreatic β cells to said patient.

Group V, claim(s) 27, drawn to a composition comprising pancreatic β cells.

Group VI, claim(s) 28 and 29, drawn to a method of forming insulin-secreting cells by cocultivating mesenchymal cells and cells capable of differentiating to insulin-secreting cells.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: They are not unified by a special technical feature.

The technical feature of Groups I-III is a pancreatic β cell-forming agent. The technical feature of Groups IV and V is pancreatic β cells. The technical feature of Group VI is insulin-secreting cells.

The expression "special technical feature" refers to those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Thus, a feature found in the prior art cannot be considered to be a special technical feature.

Pancreatic β cell-forming agents, including the species listed in claims 11-14, were known in the art at the time of the invention. Lomedico (1982, *Proceedings of the National Academy of Sciences USA* 79:5798-802; reference U) teaches cloning and expression of rat insulin. Therefore, pancreatic β cell-forming agents cannot be considered a special technical feature.

Pancreatic β cells were known in the art at the time of the invention, for example the pancreatic β cells found naturally in pancreas tissue. Therefore, pancreatic β cells cannot be considered a special technical feature.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Source of mesenchymal cells: (a) bone marrow, (b) muscle, (c) pancreas, (d) liver, (e) small intestine, (f) large intestine, (g) kidney, (h) subcutaneous tissue, (i) endometrium, (j) blood, (k) cord blood, and (l) placenta, as in claims 2 and 16, for example; elect ONE if Group I or II is elected.

Pancreatic β cell-forming agents: (m) cytokines, (n) physiologically active substances, (o) transcription factors, and (p) adhesion molecules/extracellular matrices, as in claims 5, 10, and 19, for example; elect ONE if any of Groups I-III is elected.

Cytokines: (q) hepatocyte growth factor (HGF), (r) fibroblast growth factor (bFGF)/FGF-2, (s) insulin, (t) transferrin, (u) heparin-binding EGF, (v) gastrin, (w) TGF-beta, (x) insulin-like growth factor (IGF-1), (y) parathyroid hormone-related proteins (PTHrP), (z) growth hormone, (a') prolactin, (b') placental lactogen, (c') glucagon-like peptide-1, (d')

exendin-4, and (e') KGF (keratinocyte growth factor), as in claims 6, 11, and 20, for example; elect ONE if species (m) is elected.

Physiologically active substances: (f') nicotinamide, (g') betacellulin, (h') activin A, (i') progesterone, (j') putrescine, and (k') selenium, as in claims 7, 12, and 21, for example; elect ONE if species (n) is elected.

Transcription factors: (l') PTF1a/PTF-P48, (m') Is1-1, (n') Pdx-1/IPF-1, (o') Beta2/neuroD, (p') ngn3, (q') PAX-6, (r') PAX-4, (s') H1xb-9, (t') Nkx2.2, (u') Nkx6.1, (v') HNF1-alpha, (w') HNF1-beta, and (x') HNF4-alpha, as in claims 8, 13, and 22, for example; elect ONE if species (o) is elected.

Adhesion molecules/extracellular matrices: (y') gelatin, (z') laminin, (a'') collagen, (b'') agarose, (c'') fibronectin, and (d'') ornithine, as in claims 9, 14, and 23, for example; elect ONE if species (p) is elected.

Cells capable of differentiating to insulin-secreting cells: (e'') embryonic stem cells, (f'') pancreatic stem cells, (g'') small intestinal epithelial stem cells, (h'') liver-derived stem cells, and (i'') amniotic cells, as in claim 29, for example; elect ONE if Group VI is elected.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 2, 5-14, 16-23, and 29.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart

leb

SANDRA E. SAUCIER
PRIMARY EXAMINER